IN THE UNITED STATES DISTRICT COURT

FOR THE MIDDLE DISTRICT OF TENNESSEE

NASHVILLE DIVISION

JERRY LANE BIRDSONG and BETTY BIRDSONG,	)	
Plaintiffs	)	
vs.	)	**CASE NO. _____**
ELI LILLY AND COMPANY and AMYLIN PHARMACEUTICALS, INC.,	)	**JURY DEMAND**
Defendants.	)	

COMPLAINT FOR DAMAGES

NATURE OF THE CASE

1. This is an action for personal injuries brought by Jerry Birdsong and his wife, Betty Birdsong. Jerry Birdsong consumed the widely-used diabetes prescription drug Byetta® (exenatide injection). This lawsuit asserts claims for negligence, strict product liability, breach of warranty, violation of Tennessee's Consumer Protection Act and punitive damages against each defendant. Each defendant was responsible for the design, manufacture, production, testing, study, inspection, mixture, labeling, marketing, advertising, sales, promotion, and/or distribution of Byetta®

JURISDICTION AND VENUE

2. This court has subject matter jurisdiction over this matter pursuant to 28 U.S.C. §1332 (diversity of citizenship). The matter in controversy in this civil action exceeds the sum or value of $75,000, exclusive of costs and interests, as to each defendant, and is between citizens of different states.

3. Venue in this District is proper under 28 U.S.C. §1391. The events giving rise to this cause of action occurred in substantial part in this District, where defendants transact business.

THE PARTIES

Plaintiffs

4. Plaintiff Jerry Birdsong seeks damages as a result of his consumption of defendants' Byetta®. Jerry Birdsong was prescribed Byetta® by a physician. Plaintiffs Jerry and Berry Birdsong were at all times relevant citizens and residents of Tennessee. They reside in Shelbyville, Tennessee.

Defendants

5. Defendant, ELI LILLY AND COMPANY is an Indiana corporation with its principal place of business and corporate headquarters in Indiana and regularly conducts business in the State of Tennessee. At all relevant times, Lilly was engaged in the design, manufacture, production, testing, study, research, inspection, mixture, labeling, marketing, advertising, sales, promotion, and/or distribution of pharmaceutical drugs, including Byetta® for ultimate sale and/or use in the United States of America as well as in various foreign jurisdictions. Defendant ELI LILLY AND COMPANY may be served with process at: National Registered Agents, Inc., 2300 Hillsboro Road, Suite 305 Nashville, TN 37212.

6. Defendant, AMYLIN PHARMACEUTICALS, INC. is a Delaware corporation with its principal place of business in San Diego, California, and its corporate headquarters in the State of California. Amylin is licensed to do business in all states of the United States of America including the State of Tennessee. At all relevant times, Amylin was engaged in the design, manufacture, production, testing, study, research, inspection, mixture, labeling, marketing, advertising, sales, promotion, and/or distribution of pharmaceutical drugs, including Byetta® for ultimate sale and/or use in the United States of America as well as in various foreign

jurisdictions. Defendant may be served with process at: AMYLIN PHARMACEUTICALS, INC., 9360 Towne Centre Drive, San Diego, CA 92121.

FACTUAL ALLEGATIONS

7. Jerry Birdsong took defendants' Byetta® when he was prescribed the drug by his physician on December 2, 2009. He was provided "samples" of the drug (in "pen" form) which he took once per day. On December 30, 2009 had a return visit to his physician's office and his dosage was increased (doubled). Before he was able to leave the office (and before taking the new prescription) he experienced (while still at the doctor's office) severe abdominal pain and was taken, emergently, to Saint Thomas Hospital in Nashville where he was diagnosed with acute severe pancreatitis. He has undergone three ERCP procedures, multiple CT scans and has suffered cysts, nausea, fevers and symptomatic aortic aneurysm. He now suffers from chronic pancreatitis.

8. This is an action to recover damages for personal injuries sustained by Jerry Birdsong (and for loss of consortium damages for his wife, Betty Birdsong) as the direct and proximate result of the wrongful conduct of the Defendants, AMYLIN PHARMACEUTICALS, INC. and ELI LILLY AND COMPANY, in connection with the designing, developing, manufacturing, distributing, labeling, advertising, marketing, promoting, and selling of the widely-used diabetes prescription drug Byetta® (exenatide).

9. Type 2 diabetes is the most common form of diabetes, afflicting 18 million Americans and 200 million people worldwide. This form of diabetes occurs when the body does not make enough insulin (a hormone needed to convert sugar and other food into energy) or cannot effectively use what it manages to produce. Further, diabetics arc prone to various problems, and have a greater risk of pancreatitis than healthy people.

10. Byetta® is a synthetic version of the exendin-4 compound, known as exenatide, which was created and marketed by Amylin and Lilly. Byetta® is designed to treat persons with type 2 diabetes by helping to: (1) enhance the body's ability to release insulin only in response to

elevated levels of glucose, thereby reducing the likelihood that glucose levels will be too high or too low; (2) reduce the release of blood-sugar raising hormone glucagons; (3) slow rate of nutrient absorption; (4) promote satiety; and (5) reduce food intake. On April 28, 2005, Amylin received FDA approval for its New Drug Application No. 21-773, to market Byetta® to improve glycemic control in patients with type 2 diabetes mellitus who have not achieved adequate glycemic control on metformin, a sulfonylurea, or a combination of metformin and a sulfonylurea.

11. Byetta® had total net product sales of $430 million in the United States in 2006 which increased to $636 million in 2007. In 2006, Byetta® received a marketing authorization in the European Union as add-on therapy to improve blood sugar control in patients with type 2 diabetes who had not achieved adequate glycemic control using metformin and/or sulfonylurea and began marketing in Europe in 2007. In October 2007, the FDA issued an Alert for Healthcare Professionals concerning a suspected association between being treated with Byetta® and acute pancreatitis. The FDA Alert was issued after the agency reviewed 30 post marketing reports of acute pancreatitis in patients that had be treated with Byetta®. In those reports there were no hemorrhagic or necrotizing pancreatitis; however, 5 patients had developed serious complications and 22 patients indicated that their conditions had improved after discontinuance of the drug. Moreover, when Byetta® was reintroduced, in three reports the symptoms of acute pancreatitis returned. The FDA specifically requested that Amylin include information about acute pancreatitis in the PRECAUTIONS section of the product label, and Amylin agreed.

12. On August 18, 2008, the FDA issued a further Information for Healthcare Professionals concerning Byetta®. Subsequent to the October 2007 Alert, the FDA had received reports of 6 cases of hemorrhagic or necrotizing pancreatitis in patients being treated with Byetta®. Further, all of the 6 patients were hospitalized and two patients had died. The FDA issued a warning that Byetta® should be discontinued if pancreatitis is suspected and that the FDA was working with Amylin to add stronger and more prominent warnings on the product labeling in reference to the risk of acute hemorrhagic or necrotizing pancreatitis. Oddly, on

September 9, 2008, Amylin released a new study at the European Association for the Study of Diabetes in Rome in an effort to demonstrate that Byetta® was better than Januvia, a Merck manufactured diabetes drug.

13. Defendants' Byetta® can cause acute pancreatitis, and hemorrhagic or necrotizing pancreatitis leading to death. Not only were Defendants aware of the dangers posed by Byetta®, but data from adverse event reports continued to be made available to Defendants. Yaron Werber of Citi Investment Research stated that Byetta® causes approximately quadruple the number of instances of pancreatitis that its competitor's drug Januvia. Werber stated that based upon the total number of prescriptions, out of every 100,000 patients who were treated with Byetta® about 6.49 over time developed acute pancreatitis compared with 1.61 out of 100,000 for Januvia.

14. Despite Defendants' longstanding knowledge of these dangers, Byetta®'s label failed to warn and disclose to consumers that Byetta® significantly increased the risk of acute pancreatitis, and hemorrhagic or necrotizing pancreatitis which may lead to death. Furthermore, the proper and effective use of Byetta® by Plaintiff was impaired due to Defendants' failure to warn of Byetta®'s defects and Defendants failure to properly and adequately set forth such warnings in Byetta®'s drug labeling.

15. Defendants knew of these dangerous defects in Byetta® from the many trials which they performed and to which they had access and from their own analysis of these studies, but took no action to adequately warn or remedy the defects, but instead concealed, suppressed and failed to disclose these dangers. Even in the face of the FDA Alerts to Healthcare Professionals.

16. Not only did Defendants failed to adequately disclose in their labeling or advertising that Byetta® is actually dangerous for diabetics, Defendants have represented they manufacture and/or sell safe and dependable pharmaceuticals with safety as their first concern.

17. Based on these representations, upon which Plaintiff relied, including the omission from the Byetta® labeling of a significantly increased risk of acute pancreatitis, and hemorrhagic or necrotizing pancreatitis which may lead to death, Plaintiff purchased and ingested Byetta®

believing that the drug would be safe and effective.

18. In fact, however, Byetta® poses significant safety risks due to defects in its chemical design and inadequate labeling.

19. Defendants failed to warn or inform consumers, such as Plaintiff or Plaintiff's prescribing physician, of the known defects in Byetta® including significantly increased risk of acute pancreatitis, and hemorrhagic or necrotizing pancreatitis which may lead to death, fraudulently concealed these defects and made misrepresentations to the damage and detriment of Plaintiff.

20. As a result of Defendants' omissions and/or misrepresentations, Plaintiff used Byetta® and suffered acute pancreatitis on December 30, 2009 and thereafter and faces lifetime physical and financial damages including pain and suffering.

CLAIMS FOR RELIEF

First Claim Against All Defendants

(Negligence)

21. Plaintiff readopts and realleges the allegations set forth in paragraphs 1 through 20 as though fully set forth herein.

22. At all times hereinafter mentioned, Defendants were under a duty to exercise reasonable care in the design, manufacture, testing processing, marketing advertising, labeling, packaging distribution, and sale of Byetta®, and Defendants knew or should have known that Byetta® was not safe and that the user could sustain injuries and harm from the drug.

23. Defendants negligently, recklessly, grossly negligently, wantonly and willfully displayed a morally culpable and conscious disregard of the rights of others in that they failed to exercise reasonable care and failed to fulfill the above-stated duty by the manner that Defendants, directly and indirectly, advertised, marketed and promoted Byetta® for the treatment of diabetes, even though Byetta®, in fact, was not reasonably safe for such use.

Furthermore, Defendants failed to adequately warn of the increased risk of acute pancreatitis, and hemorrhagic or necrotizing pancreatitis which may lead to death, which Defendants knew or should have known about.

24. Defendants were further negligent, reckless, grossly negligent, wanton and willfully displayed a morally culpable and conscious disregard of the rights of others by manufacturing, distributing, selling, advertising, marketing and promoting Byetta® even though such drug was not safe or effective for any purpose because it significantly increased the risk of acute pancreatitis, and hemorrhagic or necrotizing pancreatitis which may lead to death and by failing to adequately warn the public of such risks.

25. The aforesaid incident and the injuries sustained by Plaintiff were caused by or were contributed to by the negligence, recklessness, gross negligence, wantonness, willfulness, and conscious and callous disregard of the safety of the public, including Plaintiff, on the part of Defendants in the design, manufacture, distribution, advertising, marketing and promoting of Byetta® as being safe and effective in the treatment of diabetes, and by inducing the public, including Plaintiff, and Plaintiffs prescribing physician, to believe that Byetta® was effective in the treatment of the causes and symptoms of diabetes.

26. Defendants were further negligent, reckless, grossly negligent, wanton and willfully displayed a morally culpable and conscious disregard of the rights of others by manufacturing, distributing, selling, advertising, marketing and promoting Byetta® even though such drug was not safe or effective for any purpose and by failing to adequately warn the public of risks.

27. Defendants have an ongoing duty of pharmacovigilance. As part of this duty, Defendants are required to continually monitor, test, and analyze data regarding the safety, efficacy, and prescribing practices of its marketed drugs, including Byetta®. Defendants

continually received reports from their own clinical trials, practicing physicians, individual patients and regulatory authorities concerning adverse events that occur in patients taking Byetta® and Defendants' other marketed drugs. Furthermore, Defendants continue to conduct clinical trials for its marketed drugs long after the drug is approved for use. Defendants have a continuing duty to inform doctors, regulatory agencies, and the public of new safety and efficacy information they learn, or should have learned, about their marketed drugs once that information becomes available to Defendants, whether through Defendants' clinical trials, other outside sources or pharmacovigilance activities. Specifically, when Defendants learn, or should have learned, of new safety information associated with its marketed drugs, Defendants have a duty to promptly disseminate that data to the public. Defendants also have a continuing duty to monitor epidemiology and pharmacovigilance data regarding their marketed drugs and promptly report any safety concerns that arise through epidemiologic study or data.

28. Defendants were further negligent and breached this continuing duty of pharmacovigilance with respect to Plaintiff. Defendants, through clinical trials and other adverse event reports, learned that there was a serious problem associated with Byetta® use and failed to inform doctors, regulatory agencies and the public of this risk. Defendants have the means and the resources to perform their pharmacovigilance duties for the entire time Byetta® has been on the market in the United States.

29. Defendants failed to comply with the FDA postmarketing reporting requirements under 21 C.F.R. § 314.80(c) by, *inter alia*, failing to report each adverse drug experience concerning Byetta® that is both serious and unexpected, whether foreign or domestic, as soon as possible but in no case later than 15 calendar days after initial receipt of the information by defendants, failing to promptly investigate all adverse drug experiences concerning Byetta® that

are the subject of these postrnarketing 15-day Alert reports, failing to submit follow-up reports within 15 calendar days of receipt of new information or as requested by FDA, and, if additional information was not obtainable, failing to maintain records of the unsuccessful steps taken to seek additional information.

30. Defendants' failure to perform adequate pharmacovigilance and failure to comply with the postrnarketing requirements of FDA regulations is evidence of Defendants' negligence and constitutes negligence *per se.*

31. Defendants failed to develop and act upon written procedures for the surveillance, receipt, evaluation, and reporting of postmarketing adverse drug experiences to the FDA. Defendants failed to exercise reasonable care in the design, manufacture, testing, processing, marketing, advertising, labeling, packaging, rebranding. distribution and/or sale of Byetta® in one or more of the following respects:

a) Designing, marketing, processing, advertising, packaging, distributing and/or selling a product that Defendants knew, or should have known, carried the risk of serious; life-threatening side effects;
b) Failing to adequately test the product prior to placing the drug Byetta® on the market;
c) Failing to use care in designing, developing and manufacturing their product so as to avoid posing unnecessary health risks to users of such product;
d) Failing to conduct adequate pre-clinical testing and post-marketing surveillance to determine the safety of Byetta®;
e) Failing to advise consumers, such as Plaintiff, that consumption of Byetta® could result in severe and disabling side effects, including but not limited to acute pancreatitis, and hemorrhagic or necrotizing pancreatitis and death;
f) Failing to advise the medical and scientific communities of the potential for severe and disabling side effects, including but not limited , including but not limited to acute pancreatitis, and hemorrhagic or necrotizing pancreatitis and death;
g) Failing to provide timely and/or adequate warnings about the potential health risks associated with the use of Byetta®; and
h) Any and all other acts of negligence with respect to Byetta® which may be shown at trial.

32. At all times hereinafter mentioned, upon information and belief, the above-described culpable conduct by Defendants was a proximate cause of injuries sustained by Plaintiff.

33. At all times hereinafter mentioned, Plaintiff did not contribute to his injuries by reason of any negligence or culpable conduct on his part.

34. As a result of the aforesaid occurrence, and the injuries sustained by Plaintiff resulting therefrom, Plaintiff suffered extensive monetary and pecuniary losses, and other compensatory damages were also incurred and paid out, including necessary medical, hospital, and concomitant expenses. In addition, Plaintiff was deprived of a chance for safe and effective and/or successful treatment.

Second Claim Against All Defendants

(Strict Liability)

35. Plaintiff readopts and realleges the allegations set forth in paragraphs 1 through 20 as though fully set forth herein.

36. At all times hereinafter mentioned, the drug Byetta® was not suited for the treatment of diabetes, and was not safe and effective for the treatment of diabetes, even though Defendants directly and indirectly advertised, marketed and promoted Byetta® for such use.

37. At all times hereinafter mentioned, the drug Byetta® was not safe and was not suited for the purposes for which Defendants, directly and indirectly, advertised, marketed and promoted the drug at the time Defendants designed, manufactured, distributed and sold the drug and placed the drug in the stream of commerce.

38. Byetta® was defective and unreasonably dangerous when it left control of Defendants in one or more of the following manners:

a) The risk associated with use of Byetta® far outweighed the utility derived from using the medication;
b) Defendants failed to provide adequate warnings regarding the hazards associated with the use of Byetta®;
c) Defendants' product was defectively designed and unreasonably dangerous in

design and composition in that other medications could achieve similar results without the risks presented by Byetta®; and

d) Byetta® failed to comply with express warrantees that the product was safe and effective for human consumption.

39. Defendants were in the business of designing, developing, manufacturing, rebranding, labeling, marketing, distributing and/or selling Byetta®.

40. Defendants sold and/or distributed Byetta® in a condition that posed unreasonable risks from reasonably anticipated use. Byetta® was expected to and did reach Plaintiff without substantial change in condition from the time that it left the control of Defendants.

41. The defective conditions alleged herein rendered Byetta® unreasonably dangerous to Plaintiff and proximately caused the injuries and damages for which this lawsuit seeks recovery.

42. The Byetta® ingested by Plaintiff was defective and unreasonably dangerous when it left the control of Defendants.

43. The unreasonably dangerous characteristics of Byetta® proximately caused the injuries and damages for which recovery is sought.

44. Defendants knew, or in the light of reasonably available knowledge, should have known, of the danger in Byetta® that caused the damage for which recovery is sought. The ordinary user or consumer of Byetta® would not realized such dangers.

45. Defendants neglected to provide Plaintiff with warnings that reasonably could have been expected to catch the attention of a reasonably prudent person under similar circumstances taking into account the characteristics of, and the ordinary knowledge common to an ordinary consumer who purchases the product. Further, Defendants failed to provide warnings which could accurately advise an ordinary consumer of the scope, severity and likelihood of serious injury resulting from use of their product. Had such warnings been provided, the injuries and damages sustained by Plaintiff could have been avoided.

46. Defendants neglected to provide Plaintiffs prescribing physician with adequate warnings to accurately advise such physician of the increased severity and likelihood of serious injury resulting from the prescribing and ingestion of Byetta® to patients such as Plaintiff.

47. Defendants' product failed to function as expected and there existed feasible design alternatives equally effective and useful that would have had a reasonable probability of preventing the harms sustained by Plaintiff.

48. At all times hereinafter mentioned, upon information and belief, Defendants assumed a strict products liability to users and to persons using Byetta®, including Plaintiff, who sustained injuries, harm and damages by reason of the use of Byetta® for purposes directly and indirectly advertised, marketed, and promoted by Defendants, including for the treatment of diabetes.

Third Claim Against All Defendants

(Fraudulent Misrepresentation)

49. Plaintiff readopts and realleges the allegations set forth in paragraphs 1 through 20 as though fully set forth herein.

50. Defendants widely advertised and promoted Byetta® as a safe and effective medication.

51. Defendants have a duty to disclose material information about serious side effects to consumers such as Plaintiff. Additionally, by virtue of Defendants' partial disclosures about the medication, in which Defendants touted Byetta® as safe and effective treatment, Defendants had a duty to disclose all facts about the risks of use associated with the medication, including the potential for the medication to cause acute pancreatitis, and hemorrhagic or necrotizing pancreatitis and death. Defendants intentionally failed to disclose this information for the purpose of inducing consumers, such as Plaintiff, to purchase Defendants' dangerous product.

52. Had Plaintiff been aware of the hazards associated with Byetta®, Plaintiff would not have consumed the product that led proximately to Plaintiff's adverse health effects.

53. Defendants' advertisements regarding Byetta® made material misrepresentations to the effect that Byetta® was a safe and effective treatment, which misrepresentations Defendants knew to be false, for the purpose of fraudulently inducing consumers, such as Plaintiff, to purchase such product. Plaintiff relied on these material misrepresentations in deciding to

purchase and consume Byetta® to his detriment.

54. The damages sustained by Plaintiff were a direct and foreseeable result of, and were proximately caused by Defendants' misrepresentations, concealment and omissions.

55. Defendants' conduct was willful, wanton, and reckless. Based on the intentionally dishonesty nature of Defendants' conduct, which was directed at Plaintiff and the public generally.

56. Defendants should also be held liable for punitive damages.

57. Any applicable statutes of limitation have been tolled by Defendants' knowing and active concealment and denial of the facts alleged herein. Plaintiff and other members of the public who were prescribed and ingested Byetta® for the treatment of diabetes have been kept in ignorance of vital information essential to the pursuit of these claims, without any fault or lack of diligence on their part, and could not reasonably have discovered the fraudulent nature of Defendants' conduct, and information and documents concerning the safety and efficacy of Byetta®. Furthermore, due to the aforesaid allegations, Plaintiff may rely on the discovery rule in pursuit of this claim.

Fourth Claim Against All Defendants

(Strict Liability: Rest. 2nd § 402B)

58. Plaintiffs reallege all previous paragraphs.

59. Section 402B of the Restatement (Second) of Torts provides that a defendant engaged in the business of selling chattels who, by advertising, labels, or otherwise, makes to the public a misrepresentation of a material fact concerning the character or quality of a chattel sold by him is subject to liability for physical harm to a consumer of the chattel caused by justifiable reliance upon the misrepresentation, even though it is not made fraudulently or negligently, and the consumer has not bought the chattel from or entered into any contractual relation with the seller.

60. Defendants misrepresented Byetta® for the reasons set forth in Plaintiff's Third Claim for relief (fraudulent misrepresentation).

61. As a direct and proximate result of each defendant's conduct, plaintiff suffered the injuries and damages specified herein.

Fifth Claim Against All Defendants

(Breach of Warranty)

62. Plaintiff readopts and realleges the allegations set forth in paragraphs 1 through 20 as though fully set forth herein.

63. At all times hereinafter mentioned, upon information and belief, Defendants, by directly and indirectly advertising, marketing and promoting Byetta® for the treatment of diabetes, and by placing this drug in the stream of commerce knowing that Byetta® would be prescribed for the treatment of diabetes, in reliance upon the representations of Defendants, expressly warranted to all foreseeable users of this drug, including Plaintiff, that Byetta® was safe and effective for the treatment of diabetes.

64. Defendants impliedly warranted in manufacturing, distributing, selling, advertising, marketing and promoting Byetta® to all foreseeable users, including Plaintiff, that Byetta® was safe and effective for the purposes for which it had been placed in the stream of commerce by Defendants, including for the treatment of diabetes, and that Byetta® was reasonably safe, proper, merchantable and fit for the intended purposes, including for the treatment of diabetes.

65. At all times hereinafter mentioned, Plaintiff relied upon the aforesaid express and implied warranties by Defendants.

66. At all times hereinafter mentioned, Plaintiff's use of Byetta® prior to and up to the time of the above-described incident was consistent with the purposes for which Defendants directly and indirectly advertised, marketed and promoted Byetta®, and Plaintiff's use of Byetta® was reasonably contemplated, intended and foreseen by Defendants at the time of the

distribution and sale of Byetta® by Defendants, and, therefore, Plaintiff's use of Byetta® was within the scope of the above-described express and implied warranties.

67. Defendants breached the aforesaid express and implied warranties because Byetta® was not safe and effective for the treatment of diabetes, and because Plaintiff's use of Byetta® for the treatment of diabetes, caused or contributed to the incident described herein.

68. Plaintiff gave appropriate notice to Defendants of the breach of the aforesaid express and implied warranties or such notice was otherwise excused.

Sixth Claim Against All Defendants

(Violation of Tennessee Consumer Protection Act of 1977)

69. Plaintiff readopts and realleges the allegations set forth in paragraphs 1 through 20 as though fully set forth herein.

70. Defendants knowingly, willfully and intentionally engaged in unlawful, unfair, unconscionable, deceptive and fraudulent acts and practices injurious to the public interest, in violation of Tenn. Code Ann. § 47-18-101 *et seq.*, for the purpose of influencing and inducing physicians and medical providers to prescribe Byetta® to patients/consumers such as Plaintiff, and taking advantage of the lack of knowledge, ability, experience or capacity of such patients/consumers to a grossly unfair degree, and causing such patients/consumers to purchase, acquire and use Byetta® for treatment of diabetes, as prescribed by their physicians and medical providers.

71. By reason of the Defendants' unlawful, unfair, unconscionable, deceptive and fraudulent acts and practices, reasonable patients/consumers acting reasonably, such as Plaintiff, suffered acute pancreatitis on February 25, 2006, sustained renal failure, and faces a lifetime of sustained physical and financial damages including pain and suffering.

72. By reason of the facts and premises aforesaid, Plaintiff sustained actual damages in a sum which exceeds the jurisdictional limits of all lower courts which would have jurisdictional limits of this matter, and Plaintiff seeks treble the amount fixed by the verdict, together with reasonable attorney's fees and costs.

Seventh Claim Against All Defendants

(General Damages)

73. Plaintiff readopts and realleges the allegations set forth in paragraphs 1 through 20 as though fully set forth herein.

74. Plaintiff has been injured in many ways as a result of Defendants' actions. Plaintiff is alleging and can prove serious health problems associated with the use of Defendants' diabetes prescription drug Byetta® (exenatide)as described above.

75. Plaintiff, who has suffered from pancreatitis, suffered in the past, and it is anticipated will suffer in the future, medical testing, biopsies, invasive exploratory surgeries, treatments, medical monitoring, pain, suffering, mental anguish, physical impairment, medical bills and expenses as well as loss of wage earning capacity.

Eighth Claim Against All Defendants

(Loss of Consortium)

76. Plaintiffs re-allege all previous paragraphs.

77. Plaintiff Betty Birdsong should be awarded monetary damages for the loss of spousal services, society and companionship.

Ninth Claim Against All Defendants

(Punitive Damages)

78. Plaintiffs re-allege all previous paragraphs.

79. Each defendant's actions, described above, were performed with malice and in reckless disregard for the rights of plaintiff Jerry Birdsong and other patients who took defendants' Byetta®. Each defendant's failure to investigate the harms of Byetta® has resulted in numerous cases of acute pancreatitis.

80. At a minimum, each defendant's acts and omissions, when viewed objectively from the standpoint of each defendant at the time of their occurrence, involved an extreme degree of risk, considering the probability and magnitude of the potential harm to others. Each defendant had actual and subjective awareness of the risk involved but nevertheless preceded to market Byetta® with conscious indifference to the rights, safety or welfare of others, including plaintiffs. Accordingly, plaintiffs are entitled to punitive damages against each defendant.

PRAYER FOR RELIEF

81. WHEREFORE, plaintiffs, jointly and severally, seeks judgment in their favor against each defendant as follows:

a. Economic, non-economic and punitive damages in an amount in excess of $75,000 as to each defendant as provided by law and to be supported by the evidence at trial;

b. An award of attorneys' fees and costs of suit, as provided by law;

c. Such other legal and equitable relief as this Court deems just and proper.

JURY DEMAND

Plaintiffs request trial by jury.

DATED this 14th day of December, 2010.

Respectfully Submitted,

By: 

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